

K965044

JUN 16 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name: EPI for the Gyrex Prestige and Privilege systems.

1.2 Classification Name: Magnetic Resonance Diagnostic Device

1.3 Submitter: Elscint, Inc., 505 Main St., Hackensack, NJ 07601

1.4 510(k) Number: _____.

2. Device Modification Description

The modification is a new imaging sequence referred to as Echo Planar Imaging (EPI). EPI is an imaging technique which produces multiple gradient echoes after an initial RF excitation, thereby allowing faster imaging than standard gradient echo techniques.

3. Predicate Devices: Gyrex 2T Prestige system (k945791), Gyrex Privilege system (k954039).

4. Safety

- The MRI safety parameters, SAR, dB/dt, B₀, and acoustic noise, are unchanged by the current modification.
- Electrical, mechanical, and biocompatibility safety issues do not apply to the current modification.
- No new software hazards have been introduced, so the software level of concern remains minor.
- The current modifications do not affect the site planning, installation, or service manuals, and do not require any new safety labeling.

5. Effectiveness

The EPI sequences produce images that are comparable with those produced using other imaging sequences. The EPI sequences are limited in resolution, but they are faster than other imaging sequences which makes them useful for particular applications.

6. Substantial Equivalency Statement

The FDA recommended MRI safety limits are not exceeded, and the effectiveness of the modified devices is similar to that of the predicate devices. It is Elscint's opinion that the Prestige and Privilege systems with the new EPI sequences are substantially equivalent to their predicate devices in terms of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1997

Mr. Beny Sherer
Safety Officer
Elscent, Inc.
86 Orchard Street
Hackensack, NJ 07601

Re: K965044
EPI for Gyrex Prestige and Privilege MRI Systems
Dated: March 24, 1997
Received: March 25, 1997
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Sherer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: EPI for the Gyrex Prestige and Privilege MRI Systems

Indications For Use:

Whole Body Magnet Resonance Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Heyman
(Division Sign-Off)

**Division of Reproductive, Abdominal, ENT,
and Radiological Devices**

0(k) Number K965044

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use_____